AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 09/069703 Filing Date: April 29, 1998

Title: Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces

## In the Claims

Page 2

Dkt: 1195.335US1

Please amend the claims as follows:

- 1. (Previously Presented) A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, and a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose.
- 2. (Original) The pharmaceutical carrier device of claim 1, wherein said first watererodable layer comprises an alkyl cellulose or hydroxyalkyl cellulose and a bioadhesive polymer.
- 3. (Previously Presented) The pharmaceutical carrier device of claim 1, wherein said first water-erodable adhesive layer comprises a film forming polymer selected from the group consisting of hydroxyethyl cellulose, hydroxypropyl cellulose hydroxypropylmethyl cellulose, hydroxyethyl methyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, ethylene oxide-propylene oxide co-polymers, collagen, gelatin, albumin, polyaminoacids, polyphosphazenes, polysaccharides, chitin, and chitosan, alone or in combination, and a bioadhesive polymer selected from the group consisting of polyacrylic acid, polyvinyl pyrrolidone, and sodium carboxymethyl cellulose, alone or in combination.
  - 4. (Canceled)
- 5. (Original) The pharmaceutical device of claim 1, wherein a pharmaceutical is incorporated with said first water-erodable adhesive layer.
- 6. (Original) The pharmaceutical device of claim 1, wherein said layered film has two layers and a total thickness of from 0.1 mm to 1 mm.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 09/069703 Filing Date: April 29, 1998

Title: Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces

Page 3 Dkt: 1195.335US1

7. (Original) The pharmaceutical device of claim 1 which further comprises a third layer between said first adhesive layer and said second backing layer and wherein said third layer is a water-erodable, adhesive layer which has a surface area sufficient to encompass said first adhesive layer and contact the mucosal surface.

- 8. (Original) The pharmaceutical device of claim 7, wherein a pharmaceutical is incorporated with said first adhesive layer.
- 9. (Original) The pharmaceutical device of claim 1, wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device.
- 10. (Currently Amended) The pharmaceutical device of claim 9 A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, and a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, wherein said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose, and wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device, wherein the component is a water-based emulsion of polylactide, polyglycolide, lactide-glycolide copolymers, poly-∈-caprolactone, polyorthoesters, polyanhydrides, ethyl cellulose, vinyl acetate, cellulose acetate, or polyisobutylene, alone or in combination.

## 11. (Canceled)

12. (Original) The pharmaceutical device of claim 7, wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device.

Page 4 Dkt: 1195.335US1

13. (Currently Amended) The pharmaceutical device of claim 12 A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, and a pharmaceutical incorporated with said first layer, said second layer, or both layers, a third layer between said first adhesive layer and said second backing layer, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, wherein said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose, wherein said third layer is a water-erodable, adhesive layer which has a surface area sufficient to encompass said first adhesive layer and contact the mucosal surface, wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device, wherein the component is a water-based emulsion of polylactide, polyglycolide, lactide-glycolide copolymers, poly-∈-caprolactone, polyorthoesters, polyanhydrides, ethyl cellulose, vinyl acetate, cellulose acetate, or polyisobutylene, alone or in combination.

## 14. (Canceled)

- 15. (Original) The pharmaceutical device of claim 1, wherein said pharmaceutical incorporated within said first layer, said second layer, or both layers comprises an anti-inflammatory analgesic agent, a steroidal anti-inflammatory agent, an antihistamine, a local anesthetic, a bactericide, a disinfectant, a vasoconstrictor, a hemostatic, a chemotherapeutic drug, an antibiotic, a keratolytic, a cauterizing agent, an antiviral, an antirheumatic, an antihypertensive, a bronchodilator, an anticholinergic, an antiemetic, a hormone, a macromolecule, a peptide, a protein, or a vaccine alone or in combination.
- 16. (Currently Amended) The pharmaceutical device of claim 1, wherein said first watererodable adhesive layer A pharmaceutical carrier device comprising a layered flexible film
  having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a
  second, water-erodable non-adhesive backing layer, and a pharmaceutical incorporated with said

Page 5 Dkt: 1195.335US1

first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, is free of a plasticizer and comprises hydroxypropyl cellulose, hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose; and wherein said pharmaceutical comprises dyclonine HCl.

- 17. (Previously Presented) A layered flexible film disk which adheres to mucosal surfaces for the localized delivery of a pharmaceutical, comprising a first water-erodable adhesive layer and a second, water-erodable non-adhesive backing layer, wherein said pharmaceutical or combination of pharmaceuticals is incorporated with said first adhesive layer, or said second non-adhesive backing layer, or both said first adhesive layer and said second nonadhesive backing layer, and wherein said first water-erodable adhesive layer comprises a filmforming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose, said layered flexible film having a total thickness of from 0.1 mm to 1 mm.
- 18. (Original) The layered film disk of claim 17, wherein said pharmaceutical or combination of pharmaceuticals comprises an anti-inflammatory analgesic agent, a steroidal antiinflammatory agent, an antihistamine, a local anesthetic, a bactericide, a disinfectant, a vasoconstrictor, a hemostatic, a chemotherapeutic drug, an antibiotic, a keratolytic, a cauterizing agent, an antiviral, an antirheumatic, an antihypertensive, a bronchodilator, an anticholinergic, an antiemetic, a hormone, a macromolecule, a peptide, a protein, or a vaccine, alone or in combination.

Claims 19-32 (Canceled).

33. (Currently Amended) The carrier device of claim 1 A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 09/069703 Filing Date: April 29, 1998

Title: Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces

Page 6 Dkt: 1195.335US1

and a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodable non-adhesive backing layer comprises hydroxyethyl cellulose and wherein the carrier device has a solvent content of from about 1 to about 15 % by weight.

34. (Previously Presented) A layered flexible film that adheres to mucosal surfaces for the delivery of a flavoring agent to the oral cavity comprising a first water-soluble adhesive layer and a second water-soluble non-adhesive backing layer, wherein said first water-soluble adhesive layer comprises a film-forming polymer and a bioadhesive polymer and is free of a plasticizer, and said second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose, and wherein said flavoring agent is incorporated with said first water-soluble adhesive layer, with said second water-soluble non-adhesive backing layer, or with both said layers.